



**VIA CERTIFIED MAIL**

Food and Drug Administration  
555 Winderley Pl., Ste. 200  
Maitland, FL 32751

**WARNING LETTER**

FLA-03-04

October 16, 2002

Jorge Diaz, President  
D&D Catering Inc.  
D/b/a Los Vinaleros Catering  
267 West 28<sup>th</sup> Street  
Hialeah, Florida 33012

Dear Mr. Diaz:

We inspected your firm located at the above address on June 17-19, 2002 and found that you have serious deviations from the Seafood HACCP regulations (21 CFR Part 123). These deviations cause your ready-to-eat tuna fish salad sandwich products to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). In accordance with 21 CFR 123.6(g), failure of a processor to have and implement a HACCP plan that complies with this section, or otherwise operate in accordance with the requirements of this part, renders your tuna fish salad sandwiches adulterated within the meaning of Section 402(a)(4) of the Act. Accordingly your tuna fish products are adulterated, in that the products have been prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth, or whereby they may have been rendered injurious to health. In addition, your ready-to-eat tuna fish salad sandwiches are misbranded within the meaning of Section 403(i)(2) of the Act in that the product labels fail to declare the common or usual names of all ingredients. You can find the Act, the seafood HACCP regulations, and the Fish and Fisheries Products Hazards and Controls Guidance, Third Edition, June 2001 through links in FDA's home page at <http://www.fda.gov>.

The seafood HACCP deviations are as follows:

- (1) You must conduct, or have conducted for you, a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur and you must have a HACCP plan that, at a minimum, lists the critical control points, to comply with 21 CFR 123.6(a) and (c)(2). However, your firm's HACCP plan for tuna fish salad sandwiches does not list the critical control point of Receiving for controlling the food safety hazard of pathogen growth and toxin formation in premixed tuna salad. A critical control point is defined in 21 CFR 123.3(b) as a "point, step, or procedure in a food process at which control can be applied and a food safety hazard can as a result be prevented, eliminated, or reduced to acceptable levels."

(2) You must have a HACCP plan that, at a minimum, lists the critical limits that must be met, to comply with 21 CFR 123.6(c)(3). However, your firm's HACCP plan for tuna fish salad sandwiches lists a critical limit of [REDACTED] at the Storage critical control point that is inadequate to control the food safety hazard of pathogen growth and toxin formation. A critical limit is defined in 21 CFR Part 123.3 (c) as "the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard."

In addition, our Investigators observed the display cooler temperature at 52.4°F while storing tuna fish salad sandwiches during our inspection. FDA recommends refrigerated storage of finished product at temperatures of 40°F or lower, which is below the minimum growth temperature of most pathogens. See Chapter 12 of FDA's Fish & Fisheries Products Hazards and Controls Guidance, Third Edition, June 2001.

(3) You must adequately monitor sanitation conditions and practices during processing, to comply with 21 CFR 123.11(b). However, your firm did not adequately monitor all of the sanitation conditions and practices required in 21 CFR 123.11(b), as evidenced by significant insanitary practices noted in the production of ready-to-eat tuna salad sandwiches including:

- The fans in the sandwich preparation room were dirty and positioned directly over the sandwich processing tables and condensate was observed dripping from the units directly onto a processing table. (21 CFR 123.11(b)(5))
- Live flies were observed in the dry storage area. Dead flies were observed on the floor of the label/packaging storage room. (21 CFR 123.11(b)(8))
- Hand-washing facilities lacked hot water, sanitary hand towels or hand drying devices, and refuse receptacles. (21 CFR 123.11(b)(4))
- There was only one toilet facility functioning for employees on the first day of the inspection. (21 CFR 123.11(b)(4))
- An employee was observed eating taco meat while preparing tacos. She did not wash and sanitize her hands and continued to make ready-to-eat sandwiches. (21 CFR 123.11(b)(3))

(4) You must have sanitation control records that document monitoring and corrections, to comply with 21 CFR 123.11(c). However, your firm maintained sanitation control records that are not adequate, as they do not include safety of water or ice that comes in contact with food or food contact surfaces, maintenance of hand washing, hand sanitizing, and toilet facilities, or control of employee's health conditions.

The labeling deviation is as follows:

(1) Our review of your finished product label for tuna fish salad sandwiches revealed that the product is misbranded in that the label fails to declare a complete and accurate list of the common or usual names of all ingredients as required by Section 403(i)(2) of the Act and 21 CFR 101.4(a)(1). Specifically, your label fails to include celery, onions, lettuce and bread ingredients. In addition, the sub-ingredients for the ingredient "mayonnaise" in your finished product label does not correspond with the ingredient statement on the raw material "mayonnaise" label observed during our inspection. Furthermore, you are responsible for ensuring that your finished product labels for tuna fish salad sandwiches identify the firm's zip code on consumer retail packages.

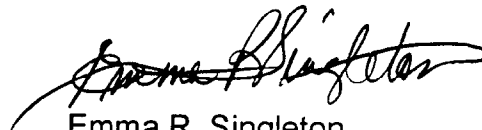
We acknowledge that your Production Manager, Mrs. Sara Diaz-Gonzales, promised corrective action and a written response letter during our inspection. However, we have not received any written response addressing these corrections. We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating.

Please respond in writing within fifteen (15) working days from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation such as a revised HACCP plan, monitoring records, sanitation records, revised product labels and other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for the delay and state when you will correct any remaining deviations.

This letter may not list all of the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations and the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

Please send your reply to the Food and Drug Administration, Attention: Shari J. Hromyak, Compliance Officer, 555 Winderley Place, Suite 200, Maitland, Florida 32751. If you have questions regarding any issue in this letter, please contact Ms. Hromyak at (407) 475-4730.

Sincerely,

A handwritten signature in black ink, appearing to read "Emma R. Singleton", written over a horizontal line.

Emma R. Singleton  
Director, Florida District